**Invitational Letter**

October 2, 2018

Dear <Name>,

The Health Level Seven® International (HL7®) Clinical Interoperability Council (CIC) has sponsored the Common Clinical Registry Framework (CCRF) project. The project aims to identify and define, via a collaborative public consensus process, definitions of key clinical data elements that are commonly used across multiple medical specialty society registries. Ultimately, these data elements will be balloted through HL7, mapped to existing terminology standards e.g., SNOMED Clinical Terms® (SNOMED CT®) and incorporated into an implementation guide based on the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard.

On behalf of the CCRF project, I’d like to invite you to review and provide feedback on a draft set of common data elements (CDEs) intended for use in clinical registries. The CDEs if implemented in registries will reduce variation in the semantic representation of common clinical concepts in registry data models. Adoption is anticipated to reduce the cost of operating and participating in registries and improve data quality. The CCRF team, with work supported in part by the Pew Charitable Trusts, has identified a proposed set of data elements from registry case report forms, data dictionaries, the U.S. Core Data for Interoperability (USCDI) set and other predicate work.

At this draft stage, the input of expert clinicians and trialists is extremely helpful. Thus, we are forming a Clinical Review Committee (CRC) to review the draft set and provide feedback on the set itself, definitions and chosen metadata. The review, which will take place during the month of October 2019, will involve examining the draft data element set of approx. 25 elements, and providing feedback via a marked-up Excel workbook. We anticipate that the review will take 1-2 hours to complete. We may also provide opportunities to discuss feedback as a reviewer group on a conference call.

Your expertise and knowledge are important to the success of this project. If you have any questions or concerns do not hesitate to contact me. We look forward to your reply by **October 12, 2018**. If you are unable to contribute to this review, please feel free to recommend other individuals for participation. Thank you so much for your consideration and support of this important effort.

Best regards,

Seth Blumenthal  
American Medical Association  
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312-464-4384

**Instructions for Clinical Review**

Our goal is to develop a standardize minimum dataset of common data elements (CDEs) for registries that represent clinical data elements that are common across most registries. Please review the data element spreadsheet, provided separately. As you review the content please keep these questions in mind:

1. Are there any data elements listed that are not relevant?
2. What relevant data elements are missing?
3. Do you agree with the provided definition for each data element?
4. Are the validation rules for each data element
   1. at the appropriate level of detail,
   2. exhaustive and
   3. mutually exclusive?

In the spreadsheet, please add your comments, recommendations and suggested edits in **column D**.

Please contact Seth Blumenthal [seth.blumenthal@ama-assn.org](mailto:seth.blumenthal@ama-assn.org) 312-464-4384 at any point during the review if you have questions.

**Description of Review Materials**

**Draft Common Data Element Specification**

For our purposes, a data element is a question and answer-format pair e.g., gender collected as ‘M’ and ‘F’. The spreadsheet contains one data element per row.

The draft data element workbook that you will be reviewing has two sheets with a set of columns. The first sheet contains general clinical data elements and the second specifies medication elements. The columns are the same on both sheets. The first three columns contain information needed to define the data element; they include:

**CLINICAL CONCEPT LABEL** is a text label associated with a data element that reflects as much as possible the data to be collected using the data element.

**CLINICAL DEFINITION** is a statement precisely specifying the meaning and scope of the data to be collected using the data element.

**CLINICAL ALLOWED VALUES** are the “pick list” or name of the coding dictionary used for the data element.

The other fields further specify the data element:

**DATABASE FIELD LABEL** is a text label specifying how the data elements are to be named in databases

**DATABASE FIELD DATA TYPE/FORMAT** is a statement specifying the data type of the database field for the element

**DATABASE FIELD BUSINESS RULES** is a statement specifying any constraints or other rules for validating the contents of the data element

Other columns contain details useful for modelers and database developers such as references to predicate work and other details.

The last two columns include:

The **CRC (Keep/Remove)** column is provided to collect your review decision as to whether or not to keep or remove the specific data element. Corresponding questions or comments for that decision can be expressed in the adjacent column (CRC Comments).

The **CRC Comments** column is provided to collect BOTH your responses to specific questions in the preceding column, as well as ANY comments or other feedback that you may have about any individual data elements. Collections of comments about specific data elements in spreadsheet form helps us make sure we associate the comment with the intended data element, and helps us make sure that all comments are addressed.

Please remember to fill out these CRC columns on both sheets with your recommendations and feedback.